Remarks

Claims 4-6, 8, and 20, 21, 23-25, 27-29, and 31-41 are pending. A copy of all of the pending claims is attached as an appendix. Applicants acknowledge with appreciation indication that claims 4-6 and 8 are allowable. Applicants note that claims 23, 24, and 25 are not under rejection and respectfully request indication that they too are allowable.

Claim 20 is drawn to a soluble tissue factor protein expressed from a nucleotide molecule encoding the amino acid sequence of Figure 2 from amino acid one to an amino acid residue between amino acid residues 219 and amino acid residue 263. Claim 31 is drawn to recombinant human tissue factor proteins expressed from a nucleotide sequence encoding an amino acid sequence which includes amino acids 1 to 219 as disclosed in Figure 2. Claim 41 is drawn to recombinant human tissue factor proteins which includes amino acids 1 to 219 as disclosed in Figure 2.

Rejections under 35 U.S.C. §112, first paragraph

The specification was objected to, and claims 20, 21, 27-29, 31-36, and 38-41 were rejected under 35 U.S.C. §112, first paragraph, on the basis that the specification, as originally filed, does not provide support for the invention as now claimed. This rejection is respectfully traversed.

The present rejection is based, essentially, on the contention that the specification does not describe what is claimed so as to reasonably convey to one skilled in the art that

applicants were in possession of the claimed tissue factor proteins at the time the application was filed. The rejection specifically asserts (page 2) that the specification is limited to descriptions of tissue factor variants that (1) lack residues 220-242, (2) have specific insertions, (3) have specific point mutations, or (4) have altered glycosylation sites.

The standard regarding what is or is not supported by the specification has been clearly articulated as requiring the specification to convey with reasonable clarity to those skilled in the art that, as of the filing date sought, the inventor was in possession of the invention, i.e., whatever is now claimed. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555 19 USPQ2d 1111, 1117 (Fed . Cir. 1991). In this regard, applicant also directs attention to MPEP § 2163.02 which describes the standard to be applied in determining if the written description requirement is satisfied. MPEP § 2163.02 reads, in pertinent part:

> Whenever the issue [of adequacy of the written description] arises, the fundamental factual inquiry is whether *a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed.* The subject matter of the claim *need not be described literally* (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement. (emphasis added)

Applicants note that the specification indicates that deletions of the transmembrane domain are not considered to be limited to deletion of only the specific amino acids of the transmembrane domain. For example, in the first full paragraph on page 15, the specification states that "a major *class* of substitutional or deletional variants *are those involving* the transmembrane, i.e. hydrophobic or lipophilic, region of tissue factor protein"

(emphasis added). Applicants assert that this sentence clearly conveys that applicants contemplated deletion variants which include both the deletion of the transmembrane region and deletion of other amino acids. The application as a whole identifies the N-terminal region of tissue factor from amino acids 1 to 219 as a separate unit of tissue factor. For example, in Figure 5 the region form amino acid 1 to 219 is depicted as the first open bar, and page 9 indicates that the filled bar in Figure 5 begins at amino acid residue 220.

In support of this is the Declaration Under 37 C.F.R. § 1.132 by William Konigsberg (previously submitted) in which Dr. Konigsberg, an expert in the field of tissue factor, analyzed the present application and concluded that the deletion of the transmembrane region as described in the application would have been understood by those of skill in the art as equivalent to a deletion of both the transmembrane region and the cytoplasmic region of human tissue factor. Dr. Konigsberg also concluded that those of skill in the art at the time the application was filed would have considered that the present inventors contemplated deletion of the entire C-terminal portion of tissue factor. Thus, applicants have provided evidence that those of skill in the art would have considered that applicants were in possession of tissue factor protein from amino acid 1 to 219 at the time of filing, thus satisfying the description requirement of 35 U.S.C. § 112, first paragraph, in regard to this segment of tissue factor.

In contrast, the rejection provides only the unsupported conclusion that the application does not convey to those of skill in the art that applicants were in possession of tissue factor

protein from amino acid 1 to 219. Essentially, the only rationale provided in the rejection in support of this conclusion is that tissue factor protein from amino acid 1 to 219 is not *explicitly* described.[1] However, as noted above and as acknowledged in the Office Action, such literal description is not required to satisfy the description requirement. All that is required is that the application reasonably convey to those of skill in the art that applicants were in possession of the claimed subject matter. The mere conclusory statement in the rejection does not outweigh the expert analysis and testimony to the contrary. Applicants submit that the un-rebutted evidence of record indicates that the application does convey that applicants were in possession of tissue factor protein from amino acid 1 to 219 at the time the application was filed.

Since the un-rebutted evidence of record indicates that the specification conveys to those of skill in the art that applicants were in possession of a tissue factor protein lacking the C-terminal region beyond amino acid 219, a claim to a tissue factor protein comprising amino acids 1 to 219 is supported by the specification within the meaning of the first paragraph of 35 U.S.C. § 112. In this regard, applicants note that there is no basis in the description requirement of 35 U.S.C. § 112 for limiting applicants to a tissue factor "consisting of" amino acids 1 to 219. Where a composition is adequately described in an application, applicants are entitled to claim the composition using open, "comprising"

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[1]Applicants also dispute that the application fails to provide an explicit description (see discussion of Figure 5 above).

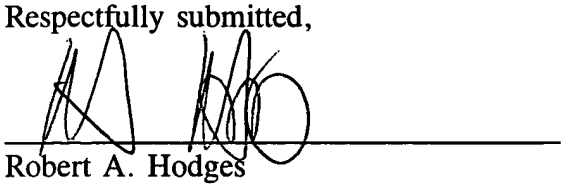
language. This can be illustrated with an example involving a carburetor. If a carburetor is adequately described in an application, applicants should be entitled to a claim to the carburetor in any setting, such as in combination with a Ford, Chrysler, or General Motors car, or in combination with any engine, through the use of open, "comprising" language, even if these combinations were not specifically described in the application. In fact, a claim to "a car comprising a carburetor..." or "an engine comprising a carburetor..." in such situations is so clearly proper as to pass without notice. The situation is the same in case of the present tissue factor proteins. Accordingly, for the above reasons, applicants assert that claims 31-41 are adequately described and supported by the specification.

In the case of claims 20, 21, and 27-29, applicants also submit that deletions "involving" the transmembrane region (see discussion above) clearly encompass deletions of less than the entire transmembrane region, since a deletion variant in which a part of the transmembrane region is deleted is clearly a deletion "involving" the transmembrane domain. The examiner should note that three groups independently and within three months of each other obtained the gene encoding human tissue factor, determined that the transmembrane region could be deleted and that a truncation could be made at amino acid 219, or shortly thereafter, to yield a soluble protein.

For all of the above reasons, applicants assert that claims 20, 21, 27-29, and 31-41 are described and supported by the specification such that the description requirement of 35 U.S.C. § 112, first paragraph, is satisfied.

Allowance of claims 20, 21, 23, 24, 25, 27, 28, 29, and 31-41, is earnestly solicited.

Respectfully submitted,



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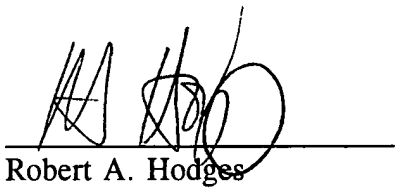
Certificate of Mailing under 37 CFR § 1.8(a)

I hereby certify that this Amendment and Response to Office Action, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.



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Date: June 17, 1998